LAMINACK, PIRTLE & MARTINES

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The Honorable Leigh Martin May
United States District Court for the Northern District of Georgia
2167 Richard B. Russell Federal Building and United States Courthouse
75 Ted Turner Drive, SW
Atlanta, GA 30303-3309

Re: Case No. 1:21-cv-03861; ***Pauline Rickard v. Teva Pharmaceuticals USA, Inc., et al;*** In the United States District Court for the Northern District of Georgia

Dear Judge May:

During the most recent pretrial conference in this case, the Court instructed Plaintiff to submit additional information on why certain categories of information are relevant to her design defect claims, as opposed to her manufacturing defect claims, which have already been voluntarily dismissed. The categories of evidence being challenged include documents and testimony related to FDA inspections as well as internal company audits.

As an initial matter, Plaintiffs believe that the evidence in question must be looked at through the lens of how it is intended to be used. Indeed, the Court noted that, while "motions in limine are sometimes good to tee up issues, [] sometimes I just have to look at the documents and see what people are actually trying to do rather than these big general concepts." 12/17/25 Tr. at 147. The Court anticipated this exact issue, especially considering that many of these documents include multiple observations (*i.e.*, FDA Inspections) and memorialize many failures on the part of Defendants (*i.e.*, Internal audits). Individual facts within the documents must be reviewed independently and in context to determine their respective admissibility and/or relevance. That is not something that can be done, or should be done, via a motion in limine addressing big, general concepts. This is especially true in the current setting, where Defendants have largely mischaracterized relevant evidence.

During the December 17th hearing, the Court heard lengthy arguments on the relevance of evidence related to the North Tonawanda facility. Defendants have continuously referred to North Tonawanda as a "manufacturing" facility and characterized all evidence tied to the facility as solely related to Plaintiff's now-dismissed manufacturing claims. This is facially inaccurate.

For the past 30+ years (spanning both the Teva and Cooper Defendants), North Tonawanda is where Paragard has been manufactured, tested, and stored, and where Defendants receive, store, and record product quality complaints, *including complaints of breakage*, relating to Paragard.[1] As the Court is well aware, complaints of product breakage—and how Defendants handled those complaints—is one of the primary focal points of this litigation. As such, the functions performed at North Tonawanda are not limited exclusively to the manufacturing process, and the evidence related to those functions—including the handling of product quality complaints—is clearly not limited solely to the manufacturing of Paragard. To be sure, these functions have been memorialized over time in various company audits as well as FDA Inspection Reports. Notably, the FDA's 2008 and 2012 inspection reports specifically discussed issues involving the trending rates of Paragard breakage and the causes of breakage. This is precisely the type of evidence that is relevant to this case, regardless of where the inspections occurred. The same is true for evidence related to the handling, analysis, and assessment of complaints related to Paragard breakage, which occurred at the North Tonawanda facility. Simply because complaints, audits, inspections, and other evidence originated, or were held, in the facility that manufactures Paragard does not remove or negate the relevance of that evidence for purposes other than proving a manufacturing defect.

Moreover, in addition to information related to complaints of breakage, the inspection reports and audits Defendants seek to wholesale exclude also identify issues related to how Paragard is stored, including its individual component parts before assembly and as a finished product. These issues are directly relevant to Plaintiff's design defect claims, as discussed within Dr. May's expert report. It is clear from these audits and inspections that the storage conditions of Paragard and its component parts were not stored according to procedures. These unsatisfactory storage conditions and the design that permits the material to sit long enough before assembly exposed Paragard and the component parts to elements that invite oxidation and deterioration. These problems exist before the product ever even reaches the assembly line and before any manufacturing conduct.

Defendants will undoubtedly argue that Paragard is a safe product that does not oxidize and/or that oxidation does not impact the product from a safety and efficacy standpoint. Defendants' argument will be based on their examination of products that have been stored in pristine, climate-controlled storage facilities. However, it is undisputed that Defendants never tested the oxidation and/or deterioration of Paragard either prior to insertion or after. *See* 30(b)(6) Deposition of Joseph DeVito at 53:13-17 ("Teva does not have a test for oxidation and that was not a test when the drug was developed. It was not a test used to evaluate the product. So no, we don't have a test on oxidation of polyethylene). Teva also testified that Paragard can oxidize. *See id.* at 51:21-25 (. . . "I can't say [oxidation] never happens because it was one of our categories for a complaint. But it's not – it's not designed to happen, but it can happen depending on how the, you know, the material can be handled.").

Ms. Rickard's Paragard was not stored in a pristine, climate-controlled facility. Her Paragard, both the finished product and its component parts, were stored in a facility that was not properly maintained. Plaintiffs will offer evidence of this environment, not to support a manufacturing claim, but to support its design defect claim by rebutting Defendants' arguments that Paragard does not oxidize, which the Court ruled is a question properly before a jury. *See* Dkt.

[1] There is also evidence that individuals, including Thomas Mehs, also have involvement with Paragard labeling.

No. 1170 at p. 10 ("Dr. Mays opines that the polymers begin oxidizing immediately, but he does not contend that it would be apparent on a new device. . . The Court agrees with Plaintiffs that Dr. Mays can . . . talk about how these materials degrade in the conditions that they are in.").

Plaintiff appreciates the Court's time and attention to this issue and is prepared to address any additional questions or concerns as needed.

Sincerely,

LAMINACK, PIRTLE & MARTINES

Buffy K. Martines
On Behalf of the Plaintiffs' Steering Committee